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Blakely, Sokoloff, Taylor & Zafman
Seventh Floor
12400 Wilshire Boulevard
Los Angeles, CA 90025-1030

EXAMINER

WALSH, DANIEL I

ART UNIT PAPER NUMBER

2876

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,367

Applicant(s)

GREEN, LARRY R.

Examiner

Daniel I Walsh

Art Unit

2876

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 20-22 is/are rejected.
- 7) ☒ Claim(s) 17-19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Receipt is acknowledged of the IDS received on 21 March 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 3, 4, and 13 recite the limitation "luminescent tag". There is insufficient antecedent basis for this limitation in the claim.

Appropriate clarification/correction is required.

3. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the label and the at least on calibration spot contain the same luminescent tag" renders the claim vague/indefinite. The Examiner has logically interpreted the claim to mean the calibration spot and label are formed on the same luminescent tag.

Appropriate clarification/correction is required.

4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what claim, claim 4 depends on, as claim 4 recites: "The method of claim 4". For examining purposes, the dependency of Claim 4 is interpreted as being dependent on Claim 1.

Appropriate clarification/correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Heninger (US 5,128,528), as cited by the Applicant.

Specifically, Heninger teaches the attachment of a luminescent label through the encoded pattern of dots of Matrix/tag 10, and a luminescent calibration spot through Reference Marker 44/Cue 46. The Matrix 10 is interpreted as a label (it is encoded with data for identification), and the Reference Marker/Cue is interpreted as a calibration spot, since it allows for interpretation of the matrix at any desired attitude with respect to the imaging equipment (col 3, lines 1+). Heninger teaches the label can be printed with fluorescent ink (col 3, lines 23+) and the marker “may be printed of any desired type and color of ink, including fluorescent inks” (col 7, lines 54+), thus teaching both the label and calibration spot are luminescent. The label/calibration spots are attached to the item (FIG. 2). Re claims 2-20 (discussed below), it is understood that as a barcode can be attached to a slide/sample holder (Domanik et al. US 5,963,368), so can the tag of Heninger, for identification purposes.

Re claim 2, the label and spot are part of the same “tag” since they encoded dots (interpreted as the label) and the spot are integral to the matrix.

Re claim 3, it has been taught above that the calibration spot and label (which make up the tag) can be fluorescent. Therefore it is understood that the matrix/tag is considered fluorescent.

Re claim 20, an item prepared by the method of claim 1 is shown in the article of FIG. 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heninger, as applied to claim 1 above.

The teachings of Heninger have been discussed above.

Heninger fails to teach the use of the specific fluorescent ink/dye Alexa Fluor 647.

Alexa Fluor dyes are well known and conventional, and are available from Molecular Probes, Eugene, Oregon, and other fluorophores known to those of skill in the art (McMillan US 6,534,645). Therefore, choosing a well-known fluorescent ink/dye for print a fluorescent label/marker, would have been obvious to an artisan of ordinary skill in the art.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heninger, as applied to claim 1 above, and further in view of Oshima et al. (US 6,303,929).

The teachings of Heninger have been discussed above.

As Heninger teaches an improvement to conventional bar code labeling, Heninger doesn't teach bar codes, but a matrix of dots. However, the use of a bar code, as opposed to a matrix of dots, would have been obvious as a matter of design variation, by using an alternative well known means to encode data.

Oshima et al. teaches a fluorescent bar code with a lead in area (interpreted as a calibration spot/area) (see FIG. 4). The lead in area is interpreted as a calibration spot since it is used to detect the intensity of the fluorescent light at the lead -in area and then compared to the intensity of the fluorescent light emitted from the data area with a reference value represented by the intensity of the fluorescent light from the lead -in area, the contents of the mark formed at the data area can advantageously be determined accurately.

At the time the invention was made, it would have been obvious to an artisan of ordinary skill in the art to combine the teachings of Heninger with those of Oshima et al.

One would have been motivated to do this to provide a machine-readable label for identification of items, as is well known and conventional in the art.

8. Claims 6-7, 9-13, 16, and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heninger, as applied to claim 1 above, in view of Noblett (US 6,471,916).

The teachings of Heninger have been discussed above.

Heninger fails to teach attaching detector molecules to at least one sample spot on the item. However, Heninger teaches that the matrices can be placed on media of any quality, cost, color, finish and reflectance (col 3, lines 21+). Therefore, it is understood that the tag can be applied to a microscope slide, for example, as taught by Domanik et al.

Re claim 6, Noblett teaches attaching one or more detect molecules to at least one sample spot on the item through “Reference or target DNA is spotted onto a glass substrate—typically a one-by three-inch glass microscope slide” (col 1, lines 38+). This is interpreted to include attaching detector molecules to at least one sample spot on the item/slide.

Re claim 7, Noblett teaches that different sample spots contain different detector molecules though “Each spot, or sample, of DNA constitutes a separate experiment” (col 1, lines 40+), interpreted as different DNA/detector molecules.

Re claims 9-11, Noblett teaches exposing the detector molecules to a sample suspected of containing one or more target compounds through “A sample of probe DNA or RNA, to which has been added the fluorophore material, is subsequently placed on the target spots on the surface of the substrate and is allowed to hybridize with the target DNA” (col 1, lines 41+). It is understood that the probe DNA/RNA is a sample containing a target compound that is applied to a sample spot on the item and that the detector molecule(s) and target compound are exposed to each other (mixed).

Re claim 12, Noblett teaches the detection of a presence of one detector molecule: target compound complex through “The experiments measure the binding affinities between the probe DNA and the target DNA to determine the similarity in molecular structure...The fluorophore added to the probe DNA emits a range of radiation energy...The brightness of the emitted radiation...is a function of the fluorophore concentration present...the brightness of a hybridized spot is an indication of the degree of similarity between the probe DNA and the target DNA” ,and that the radiation is measured by a detection system of a mircoarry scanning system (col 1, lines 52+).

Re claim 13, it is understood that the complex is tagged with the same tag since it is on the same tag. Further, it is well known and obvious to use adhesive identifiers/labels/barcodes (including luminescence) to tag an item for identification, as is well known and conventional in the art.

Re claim 16, it is well known and conventional in the art to read a label/barcode to identify the item.

Re claims 21-22, though the prior art of Heninger teaches the tag can be placed on any media (see above), which is interpreted to include a microscope slide, as is well known and conventional in the art for having a barcode (Domanik et al.), and also interpreted to include a waveguide, which is a media, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ2d 1647 (1987).

At the time the invention was made, it would have been obvious to an artisan of ordinary skill in the art to combine the teachings of Heninger with those of Noblett.

One would have been motivated to do this in order to apply an identification label to a item (slide where molecules are mixed), to provide identification information about the item, as is well known and conventional in the art.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heninger as modified by Noblett, in view of Barbera-Guillem et al. (US 6,251,616).

The teachings of Heninger as modified by Noblett have been discussed above.

Heninger and Noblett fails to teach the use of antibodies as a detector molecule.

Barbera-Guillem et al. teaches the use of antibodies as a detector molecule through "In a preferred embodiment, affinity ligands may include, but are not limited to, one or more of: anti-CD19 antibody, anti-CD20 antibody, anti-CD21 antibody, anti-CD22 antibody, anti-sTn antibody, anti-CD5 antibody, Lym-1 antibody (antibody against the B cell determinant recognized by Lym-1; see, e.g., U.S. Pat. No. 5,789,554), CDIM antibody (antibody against the B cell determinant recognized by CDIM; see, e.g., U.S. Pat. No. 5,593,676), anti-CD45R (RAhi or RO) antibody, anti-Ki-M4 antibody, and anti-DRC-1 antibody. A "detector molecule" is used herein to refer to an affinity ligand which has been coupled (using covalent or noncovalent or other means known in the art) to a detectable moiety" (col 6, lines 25+). This is interpreted to include the use of an antibody as a detector molecule as known in the art.

At the time the invention was made, it would have been obvious to an artisan of ordinary skill in the art to combine the teachings of Heninger and Noblett with those of Barbera-Guillem et al.

One would have been motivated to do this in order to have an alternative detector molecule (antibodies), as is well known and conventional in the art, for the detection of different substances.

10. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heninger and Noblett, in view of Oshima et al.

The teachings of Heninger and Noblett have been discussed above.

Though Heninger and Noblett teach measuring the light from the sample spot to determine the amount of a substance present, they fail to teach comparing the light emitted from

the calibration spot with the light from the sample spot, to determine the concentration of each target compound.

Oshima et al. teaches measuring the light from a lead-in area (FIG 4) that is used as a reference measurement for accurately determining the intensity of the light from the data area. Though Oshima et al. does not teach detector molecules and substances, it does teach the use of a calibration/lead in area to be used as a reference measurement for accurate intensity measurements. Therefore, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made, to combine the teachings of Heninger and Noblett with those of Oshima et al., in order to have a way to accurately determine the concentration (presence) of a target compound in a sample, by comparing the sample light from the calibration light, in order to more accurately measure the intensity of the light, which is indicative of the concentration of a sample, as is well known and conventional in the art.

Allowable Subject Matter

11. Claims 17-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to teach that the label, calibration spots and sample spots are attached to the item using an aldehyde cross-linking group.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: McMillan (US 6,534,645), Faklis (US 6,006,991), Domanik et al. (US 5,963,368), Liang (US 5,414,258), Sandison (US 5,838,435), Izmailov (US 6,397,150), and Takeda et al. (JP02002150478A).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Walsh whose telephone number is (703) 305-1001. The examiner can normally be reached between the hours of 7:30am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on (703) 305-3503. The fax phone numbers for this Group is (703) 308-7722, (703) 308-7724, or (703) 308-7382.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[daniel.walsh@uspto.gov]**.

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set for the in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0956.

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D. Walsh

DIW
4/2/03



MICHAEL G. LEE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800